November 4, 2015
9:00 am – 10:30 am

Department of Health
2585 Merchants Row
Conference Rm. 320P
Tallahassee, Florida 32311

IRB 2 Convened Committee
Meeting Minutes

IRB Attendance:

Carina Blackmore (Chair)

Jaime Arango (non-scientist, non-affiliated)

Daniela Chiriboga Salazar

Cheryl Clark (Expertise in Subpart B: Pregnant Women/Fetus/Neonates; and Subpart D: Children)

Jamie Forrest

Nkechi Ichite

Nina McGrew (Non-affiliated; absent)

Brenda Whittenberg (Expertise in Subpart C: Prisoners, non-affiliated)

7 of 8 members attending

Other Attendees: Robert Hood, Ph.D.

Quorum

A quorum was present. A quorum is defined as a majority of members present. The quorum also reflected the requirement outlined in 45 CFR 46.108 as well as 21 CFR 56.107. Please note that the number of members present will not always match the total number of votes on items as the total number votes reflects the number of members present in the room at the time of discussion and vote. At least one non-scientist and at least one non-affiliated member were present.

Members present by phone received all pertinent materials prior to the meeting to allow adequate time for review and request of additional information, if needed. Members present by phone actively and equally participated in the discussion of all protocols.

Conflict of Interest:

Conflict of Interest: None declared

Members did not report any:

- Compensation or payments for services (e.g., consulting fees, lecture payments, bonus, royalties, paid authorship, honoraria, gifts, or in-kind products or services) related to the research of any value, except as otherwise excluded by this policy.
- Compensation or payments for services where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
- Equity interests (stocks, stock options, security, or other ownership interests) related to the research of any value.

- Equity interests whose value when aggregated for the individual and the individual's immediate family represents more than a five percent ownership interest in any single entity.
- Equity interest related to the research in a non-publicly traded corporation of any value by the individual or a member of the individual's immediate family
- Equity interest related to the research of any amount to the researcher or any member of the researcher's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
- Intellectual property rights and interests (patents, copyrights, royalties, licensing agreements, and any other proprietary interest related to the research).
- Board or executive relationship related to the research, regardless of compensation.
- Involvement or participation in the design, conduct, or reporting of the research, including providing advice on Department registry data systems.
- Serving as the immediate supervisor of a researcher within the last year
- Any other interest that the IRB member believes would interfere with his or her ability to objectively review a protocol.
- Any travel related to research

Education:

Dr. Hood reviewed the Notice of Proposed Rulemaking to revise DHHS regulations governing protection of human participants in research. The current regulations have been in place since 1981, and the revised regulations make significant changes. The proposed revisions eliminate the requirement for continuing review of research that is not greater than minimal risk; create a new category of "excluded" research that clarifies when public health activities are not research; require single IRB review of certain federally-sponsored research studies; requires that almost all research involving human tissues have IRB approval (in contrast to the current state of affairs, where tissues that do not have identifiers are not considered to be "human subjects" and do not require IRB review); and make revisions to consent documentation; and include other changes.

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(1) Protocol Title: Strategic Timing of AntiRetroviral Treatment (START) Hillsborough CHD

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	Charurut Somboonwit, M.D.	Daniela Chiriboga-Salazar Nketchi Ichite

Meeting Discussion:

The reviewers reviewed a progress report summarizing the progress of the study during the previous review period, and determined all criteria for approval are met. The purpose of the study was to establish whether it was more effective to initiate antiretroviral therapy when the CD4 count was 500 or above, or delay initiation of therapy, and avoid side effects, until the CD4 count fell below 350. There were 16 subjects enrolled locally, all currently on retrovirals. May 2014 DSMB met, based on study found goals had been satisfied, and that there was a significant benefit in terms of HIV complications, and non-HIV complications, decided to halt study, and recommend that individuals be advised to go on medication is the best approach. So currently all subjects are on antiretrovirals. Currently all participants

are in the monitoring phase using FDA approved drugs according to standard of care. 1) Based on the fact that all participants have shifted to standard of care, the risks are no longer greater than minimal, and shifting patients to standard of care minimizes risks. 2) The risks were reasonable when the study started, and are reasonable in terms of ongoing monitoring. 3) Subject selection was based on CD4 counts; ongoing monitoring is equitable. 4) The study involves written informed consent, which continues to be appropriate, and includes a description of the reasons for changes in the research. 5) The safety monitoring plan accomplished its goals – identifying the outcome of the study early, and allowing patients to be shifted into what the study showed to be a better therapy. 6) The site has appropriate facilities, such as private exam rooms, to protect privacy. 6) The study site stores records behind locked doors, and controls access to the facility. Electronic records meet the Department's security standards, so appropriate provisions are in place to protect confidentiality of data. 8) There were no vulnerable populations in the study. The IRB determined the study can be reviewed in the future using the expedited procedure.

Total votes to approve the corrective action plan: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 0

(2) Protocol Title: Emergency Treatment of Coral Snake Envenomation (Tampa General Site)

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	Thomas Paredy, M.D.	Nketchi Ichite Jamie Forrest (pregnant women) Brenda Whittenberg (prisoner representative)

Meeting Discussion:

The reviewers reviewed a progress report summarizing the progress of the study during the previous review period, and determined all criteria for approval are met. The study is progressing normally, and there have been no new risks, no problems, no new information or publications or other significant modifications to the study in the previous year.

Patients who present with potential coral snake bites are referred to the poison control center – statewide network, which is part of the Department. This is a new greater than minimal risk study looking at a novel antivenom for coral snake bites. The currently approved antivenom is no longer being produced and available batches are expiring soon. The study will last for an indeterminate period until the antivenom is FDA approved or withdrawn from clinical trials.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111:

Risks are minimized by using procedures consistent with sound science, and are reasonable compared with other drugs in the class. Subject selection is equitable because participants are selected based on the presentation of a snake bite as opposed to race, class, gender or sex. Risks are reasonable in relationship to the importance of the knowledge to be obtained. The researcher has appropriate

qualifications and expertise because he is a practicing physician and has completed CITI courses. All applicable elements of consent and parental permission are present. The PI or co-PI obtain consent from the participant or their legal authorized representative in private exam rooms. The PI or co-PI will obtain assent from children when they are over 7 years old. The assent documents are targeted age appropriately. Safety monitoring will be conducted by an independent board and time frames for review are appropriate. Safeguards are appropriate to protect the rights and welfare of children, prisoners, pregnant women, and mentally disabled persons that participate in this study as determined via their respective subparts. No conflicts of interest were reported. The board decided that a Spanish consent form should be constructed to ensure as many people as possible are able to enter the study, consent provided. This will be provided at a later date.

Children

Category 405: The research is greater than minimal risk because it involves use of an unapproved drug. There is the prospect of direct benefit to the children because the unapproved drug has seems to be promising as a treatment for coral snake venom in children.

The risks in the research, from a medication side effects including serum sickness, anaphylactic and or anaphylactoid reactions, are justified by the potential benefit of ameliorating the effects of coral snake venom, which can be fatal.

Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child, because there is a direct benefit to the child that could not be obtained outside the research context and needs to be administered in a timely manner.

Pregnant Women

Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses. Although the protocol does not describe animal work and Phase I studies involving pregnant women, the risks appear to be consistent with other studies in the drug class and the venom from a coral snake can be deadly.

The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. Risks to the fetus are unknown but the study is likely to reduce risk of maternal death, which could impact the health of the fetus, maternal death.

Any risk is the least possible for achieving the objectives of the research because the design of the research provides alternatives of care.

Consent of the woman is obtained and documented in writing. The consent document provides information such that the mother is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. The research holds out the prospect of a direct benefit both to the pregnant woman and the fetus.

The consent of the woman is obtained because consent of the father may delay treatment.

No inducements, monetary or otherwise, will be offered to terminate a pregnancy because there is no compensation in the research and the researcher has attested no attempt will be made to terminate the pregnancy in the research.

Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. The researcher attested no attempt will be made to attempt to terminate the pregnancy in the research.

Individuals engaged in the research will have no part in determining the viability of a neonate. This is not a clinical study or study does not occur during labor where such a determination is made and the researcher attested they are not involved in determining the viability of the neonate.

Prisoners

This is a non-federally funded study that does not provide advantages to a prisoner through their participation in the research, when compared to the general living conditions of prisoners. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers since everyone receives the same treatment. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners because the selection criteria are based on a coral snake bite. The information is presented in language which is understandable to prisoners. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. The P.I. attests that “Inclusion in this study is based strictly on experiencing a coral snake bite. Inclusion will have no impact on parole boards” and will be discussed during the consent process. If the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact because participants will be treated in the hospital until they are well.

Total votes for approval: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 0

(3) Protocol Title: Multicenter, Double-Blind, Randomized, 2-Part, Dose Ranging Study to Compare the Safety, and Antiretroviral Activity of MK-1439 Plus TRUVADA™ Versus Efavirenz Plus TRUVADA™ in Antiretroviral Treatment-Naive, HIV-1 Infected Patients [MK1439-007]

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	Jose Montero, M.D.	Daniela Chiriboga-Salazar Carina Blackmore

Meeting Discussion: The study is about 13 weeks away from the conclusion of the study. The study is progressing normally, and there have been no new risks, no problems, no new information or publications or other significant modifications to the study in the previous year.

(1) Risks continue to be greater than minimal but the design remains consistent with sound research design and does not unnecessarily expose subjects to risk. (2) Risks continue to be reasonable in relation to anticipated benefits, and there have been no new risks identified in the previous year. (3) Selection of subjects is unchanged and remains equitable. (4) Consent is by long form written consent. There were several changes and additions, to clarify recruitment and side effect reporting in the precious year and and consent is appropriate. (5) A safety monitoring board monitors safety and there have been no problem. (6) Provisions to protect privacy interests of participants and confidentiality of data are unchanged and continue to be appropriate. (8) No vulnerable populations are enrolled, and inclusion criteria are unchanged from the initial approval.

Members recommended the site plan to transition patients to standard of care, in the event the sponsor does not introduce an expanded access study. Members discussed the fact that patients may have opted to go on clinical trial as alternative because they couldn't get medication, and noted that the site has a history of working with participants to continue treatment. Members were satisfied all criteria for approval continue to be met.

Total votes to approve for 12 months: (Total members voting: 7) Affirmative:7 Negative: 0 Recusal: 0 Absent:0

Meeting adjourned at 10:45